

## REMARKS

### STATUS OF CLAIMS

Claims 1-5, 10-13, 15, 17-21 and 23-46 are pending herein, claims 43-46 having been added, and claims 6-9, 14, 16 and 22 having been canceled without prejudice or disclaimer.

Claims 2-4, 12, 13, 15, 20, 21, 24, 25, 27-30 and 33-38 have been withdrawn in response to a Restriction Requirement by the Examiner.

Support for the amendment to claim 1 can be found, for example, in original claims 9, 16 and 22 and in paragraphs [00028] and [0035] of the specification as filed. (The proviso in claim 1 is rendered moot by the amendment.)

Support for new claims 43-46 can be found, for example, in original claims 7, 8, 18, 31 and 41.

No new matter is added.

### Response to Restriction

Applicant previously responded to certain of the Examiner's requests for species election with traverse.

For example, Applicant had traversed the requirement for restriction between claim 10 (microparticles are microspheres), claim 12 (at least two populations of microparticles that are of different composition from one another) and claim 13 (at least two populations of microparticles having different size distributions), citing as authority MPEP 806.04(f), which requires that claims to differing species be mutually exclusive. MPEP 806.04(f) explicitly states that "*to require restriction between claims limited to species, the claims must not overlap in scope*" (emphasis added, extraneous punctuation removed). Claims 10, 12 and 13 are clearly *not* mutually exclusive, so the requirement is improper.

The Examiner has responded by urging that searching these species would place a burden on the Examiner, pointing out reasons why database searching, searching different classes/subclasses, etc., would constitute a burden. However, even assuming solely for the sake of argument that a search of claims 10, 12 and 13 would prove to be burdensome, a burden on the Examiner, without more, is not sufficient to support a requirement for restriction. See, e.g., MPEP 803.

The Examiner also argues that there is an examination and search burden “due to the mutually exclusive characteristics of the species.” However, the species are clearly *not* mutually exclusive for the reasons noted above. Consideration of claims 12 and 13 is requested.

Applicant had also traversed the requirement for restriction between the following species:

- a. comprising adhesive and therapeutic agent (claims 1-23, 26, 29-33 and 35-42);
- b. comprising additional biodisintegrable adhesive and additional therapeutic agent (claims 24-25);
- c. comprising first and second adhesive regions (claim 27);
- d. comprising first and second different therapeutic agent (claim 28); or
- e. comprising the structure of claim 34.

Specifically, the requirement was previously traversed because forgoing species are not mutually exclusive (e.g., category a is not mutually exclusive with categories b, c, d and e; category b is not mutually exclusive categories c, d and e; etc.). For this reason, consideration of claims 24, 25, 27-30 and 34-38 is requested.

The Examiner did not respond to the preceding remarks in the Office Action.

#### **Rejection under 35 U.S.C. 102(b)**

Claims 1, 5, 9, 10, 16-19, 22, 23, 26, 31, 32, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogle et al., US 6,491,617 (Ogle). This rejection and its supporting remarks are respectfully traversed

Moreover, this rejection is believed to be moot in view of the above amendment to claim 1, which now requires microparticles, at least a portion of which are attached to the surface of the adhesive region, wherein said therapeutic agent is neither partially nor fully embedded within the microparticles. These features are neither taught nor suggested by Ogle.

Reconsideration and withdrawal of the rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

#### **Rejections under 35 U.S.C. 103(a)**

Various claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle alone or Ogle in combination with one or more additional references.

Specifically, claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Ogle. Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Pinchuk et al., US 6,545,097 (Pinchuk). These rejections and their supporting remarks are respectfully traversed.

Moreover, as noted above, claim 1, now requires microparticles, at least a portion of which are attached to the surface of the adhesive region, wherein said therapeutic agent is neither partially nor fully embedded within the microparticles. These features are neither taught nor suggested by Ogle. Nor does Pinchuk overcome these deficiencies in Ogle.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) are therefore respectfully requested.

### **CONCLUSION**

In view of the above, Applicant submits that all pending claims are in condition for allowance. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed. All fees due and owing in respect to this Amendment may be charged to deposit account number 50-1047.

Respectfully submitted,

/David B. Bonham/

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